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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,094	10/21/2005	Katsuyoshi Nagao	06854.0046	6586

22852 7590 12/04/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
MARCETICH, ADAM M	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
12/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,094	NAGAO ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,11-13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7, 11-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. PCT/JP/2004/005547, filed on 19 April 2004 has been received.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2009 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 3-7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US 4502616) in view of Peiffer; Herbert et al. (US 6068936) in view of Itoh; Takurou et al. (US 6042906).

6. Regarding claims 1, 4-7 and 12, Meierhoefer discloses an ampoule comprising:

7. [1] a flexible container body (column 3, lines 56-65 and Fig. 3, vials or ampoules 12);

8. [1] a fusion-bonded portion which seals a mouth of the container body (column 4, lines 25-36 and Fig. 3, seal 44); and

9. [1] a holder tab connected to the fusion-bonded portion for wrenching off the fusion-bonded portion (column 4, lines 25-36 and Fig. 3, key 26).

10. [1] The ampoule of Meierhoefer comprises plastic (column 3, lines 56-65), therefore it naturally follows that it is capable of preventing drug permeation.

11. [1] Meierhoefer discloses the invention substantially as claimed, see above. However, Meierhoefer lacks three or more layers as claimed [claim 1]. Peiffer discloses a multi-layered polyolefin film (col. 2, lines 49-62, col. 3, lines 7-19 especially lines 15-19), comprising three or more layers including:

12. [1] innermost and outermost layers composed of a polyolefin (col. 11, lines 12-60, especially lines 41, 42; example 1, layers B; 98.77% random ethylene-propylene copolymer; it is the Examiner's position that the remaining components do not materially affect the basic and novel characteristic of the claimed invention. See MPEP 2111.03, Transitional Phrases.

13. [1, 7] an intermediate layer composed of blends of a polyolefin and a polycycloolefin (col. 6, lines 33-39; col. 11, lines 12-60 especially lines 30-35; example 1, layer A; 94.85% by weight of isotactic polypropylene and 5.0% by weight of norbornene homopolymer);

14. [1, 12] wherein at least one of the layers is a functional layer having a gas permeation preventing capability (col. 11, lines 5-17, especially lines 13-17; water vapor and oxygen barrier properties of example 1, layer A).

15. [12] wherein the ampoule has a volume of 0.5 to 20mL (column 4, lines 7-9, volume of 5.0mL overlapping claimed range of 0.5 to 20mL).

16. [4] wherein the functional layer comprises a polyamide layer (col. 8, lines 35-45, col. 9, lines 13-25, especially line 17, antiblocking agent optionally added to inner layer, including polyamides);

17. [5, 6] wherein the functional layer comprises a polyol or polyester layer (col. 9, lines 13-25, especially line 18, polyesters, it naturally follows that polyester is a polyol);

18. [1] Regarding the functional layer, Peiffer provides the advantage of improved water vapor and oxygen barrier properties (col. 11, lines 5-17, especially lines 13-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the invention of Meierhoefer as discussed with the three layers as taught by Peiffer in order to provide improve barrier properties.

19. [1, 3-12] Regarding the limitation of a "...container body [that] is molded by holding [a] parison," Examiner notes that claims 1 and 3-12 are drawn to a device, not a method of manufacture.

20. This rejection is made in light of ***In re Thorpe***, 227 USPQ 964 (CAFC 1985) wherein product-by-process claims to a drug solution filling plastic ampoule are rejected over vials or ampoules 12 of Meierhoefer, which although may be prepared in a different manner, appears to be the same (prima facie) as the claimed product and performs the same function as the claimed product does.

21. Because of the nature of product-by process claims, the Examiner cannot ordinarily focus on the precise difference between the claimed process of molding and the disclosed vials / ampoules. It is then Applicants' burden to prove that an unobvious difference exists. See ***In re Marosi***, 218 USPQ 289, 292-293 (CAFC 1983).

22. In the instant case no Graham vs. John Deere analysis was made but rather the test set out in MPEP 706.03(e) and In re Marosi was applied while explaining why the claimed product does not patentably distinguish over the prior art under 35 USC 102/103.

23. Meierhoefer teaches that the vials or ampoules 12 comprise a polymer (col. 3, lines 56-65), but is silent as to the method of manufacture, namely being "integrally molded" and "molded by holding the parison between split mold pieces." The claimed phrase "container body . . . molded by holding" is being treated as a product by process

limitation; that is, a container that is made by molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

24. Thus, even though Meierhoefer is silent as to the process used to form the vials or ampoules 12, it appears that the product as taught by Meierhoefer would be the same or similar as that claimed; especially since both applicant's product and the prior art product comprise a polymer and are mass-produced.

25. Meierhoefer and Peiffer disclose the invention as substantially claimed, see above. However, each of Meierhoefer and Peiffer lack the claimed thickness of an intermediate layer from 11.8 to 35.3% of a total thickness as claimed [1]. Instead, Pfeiffer discloses a thickness of approximately 94% (col. 11, lines 22-26, total thickness 20 microns, outer layers each 0.6 microns, (20- 0.6 – 0.6) / 20 = 94%).

26. Examiner interprets the relative intermediate layer thickness as a result-effective variable, subject to experimentation and testing. A result-effective variable is a parameter which achieves a recognized result. These results are obtained by the determination of optimum or workable ranges of said variable through routine experimentation. The property of intermediate layer thickness forms a container with effective gas barrier properties through routine experimentation.

27. Itoh discloses a multi-layer plastic container (col. 1, lines 6-13), comprising at least three layers, the intermediate layer comprising a cyclic olefin (col. 3, lines 37-44).

Itoh adjusts the thickness of an intermediate layer within the claimed range (cols. 16-17, lines 65-5, ratio of intermediate layer to total thickness between 1:99 and 30:70 overlapping claimed range of 11.8 to 35.3%).

28. Here, Itoh demonstrates that the claimed range is also effective in preventing materials from diffusing through a barrier layer (col. 19, lines 11-14, multi-layer plastic container effective to prevent diffusion of fragrant or alcohol-containing substances). In other words, Itoh shows that the claimed thickness range also prevents diffusion of volatile substances. Also, Itoh demonstrates a container having multiple intermediate layers (col. 17, lines 18-27, especially lines 26-27, additional adhesive resin / AD layers). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the intermediate layer thickness in order to form an effective gas barrier. See MPEP 2144.05(II)(A,B). Also see in re Boesch and Slaney, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

29. Regarding claim 3, Meierhoefer discloses the invention substantially as claimed, see above. However, Meierhoefer lacks an additive as claimed [claim 3]. Peiffer discloses:

30. a layer provided as other than an innermost layer and composed of a material containing at least one additive selected from the group consisting of a colorant (col. 10, lines 51-59, col. 13, lines 33-39; corona-treated films printed with ink; it is the Examiner's position that printing places an additive on an outer layer, therefore an additive is provided on a layer other than the innermost layer); and

31. a layer provided inward of the additive-containing layer and having a drug permeation preventing capability (layer A as discussed for claim 1 above capable of preventing drug permeation). Peiffer provides the advantage of printing indicia directly on containers, which is valuable for labeling the contents of medical containers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Meierhoefer as discussed with the colorant additive as taught by Peiffer in order to label medical containers.

32. Regarding claim 11, Meierhoefer discloses an ampoule sequence including a plurality of ampoules connected to one another via severable thin wall portions (column 4, lines 45-49 and Fig. 1, separation strip 36).

33. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US 6254376) in view of Peiffer; Herbert et al. (US 6068936) in view of Itoh; Takurou et al. (US 6042906).

34. Regarding claim 13, Louviere discloses a production method for a drug solution filling plastic ampoule comprising the steps of:

35. molding a container body by holding a tubular parison between lower split mold pieces (column 5, lines 57-62 and Fig. 1, core pins 68, 70 and slide inserts 26, 28; column 9, lines 47-65). Louviere discloses forming a hollow plastic article (column 9, lines 31-34) therefore it naturally follows that that Louviere has a step of forming a void in a parison.

36. A parison is defined as a partially shaped mass of molten glass (online dictionary, "parison"). Applicant has not further defined the term "parison" in the specification, therefore it is given its plain meaning. Liquidized plastic reasonably meets the definition of "parison" in the context of plastic molding.

37. Louviere discloses a step of filling a drug solution in a container body (column 10, lines 28-37).

38. Louviere substantially discloses holding a mouth of a container body between upper split mold pieces to form a fusion-bonded portion which seals the mouth of the container body and a holder tab which is connected to the fusion-bonded portion to be used for wrenching off the fusion-bonded portion (column 9, lines 34-41 and Fig. 8, rectangular extension top 240A and nearby neck).

39. Louviere discloses the invention substantially as claimed. However, Louviere lacks a parison having three or more layers as claimed [claim 13]. Peiffer discloses a multi-layered polyolefin film (col. 2, lines 49-62, col. 3, lines 7-19 especially lines 15-19), comprising three or more layers including:

40. innermost and outermost layers composed of a polyolefin (col. 11, lines 12-60, especially lines 41, 42; example 1, layers B; 98.77% random ethylene-propylene copolymer; it is the Examiner's position that the remaining components do not materially affect the basic and novel characteristic of the claimed invention. See MPEP 2111.03, Transitional Phrases.

41. an intermediate layer composed of blends of a polyolefin and a polycycloolefin (col. 6, lines 33-39; col. 11, lines 12-60 especially lines 30-35; example 1, layer A;

94.85% by weight of isotactic polypropylene and 5.0% by weight of norbornene homopolymer);

42. wherein at least one of the layers is a functional layer having a gas permeation preventing capability (col. 11, lines 5-17, especially lines 13-17; water vapor and oxygen barrier properties of example 1, layer A).

43. See discussion of claim 1 above regarding rationale and motivation to modify Louviere in view of Peiffer.

44. Both Louviere and Peiffer lack an intermediate layer thickness overlapping the claimed range of 11.8 to 35.3% of a total thickness. Examiner interprets the intermediate layer thickness as a result-effective variable, and cites Itoh as teaching an example of the claimed range. See discussion of claim 1 above regarding rationale and motivation to modify Louviere and Peiffer in view of the intermediate layer thickness of Itoh.

45. Regarding claim 15, Louviere discloses the invention substantially as claimed, see above. However, Louviere lacks an additive as claimed [claim 15]. Peiffer discloses:

46. a layer provided as other than an innermost layer and composed of a material containing at least one additive selected from the group consisting of a colorant (col. 10, lines 51-59, col. 13, lines 33-39; corona-treated films printed with ink; it is the Examiner's position that printing places an additive on an outer layer, therefore an additive is provided on a layer other than the innermost layer); and

47. a layer provided inward of the additive-containing layer and having a drug permeation preventing capability (layer A as discussed for claim 1 above capable of

preventing drug permeation). Regarding rationale and motivation, see discussion of claim 3 above.

Response to Declaration Under 37 CFR 1.132

48. The Declaration under 37 CFR 1.132 filed 21 October 2008 is insufficient to overcome the rejection of claims 1, 3-7, 11, 12 and 13 based upon 35 USC § 103 over Meierhoefer, Pfeiffer and Louviere as set forth in the last Office action. It includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

49. Declarant has performed a test comparing two examples of plastic ampoules comprising:

- an inner layer (polyolefin), an intermediate layer (blends of polycycloolefin and polyolefin) and an outer layer (polyolefin); versus
- an inner layer (polyolefin), an intermediate layer (only polycycloolefin) and an outer layer (polyolefin).

50. The two forms of plastic ampoules were evaluated according to surface smoothness and external qualities by photographing them with a digital camera. Declarant finds that the first example, having an intermediate layer comprising both polycycloolefin and polyolefin, formed a smoother surface than the second example.

Here, Declarant has demonstrated that including both polycycloolefin and polyolefin within an intermediate layer produces ampoules with a smooth outer surface.

51. However, this declaration is insufficient to withdraw the rejection over Meierhoefer in view of Peiffer. The declaration does not demonstrate that an unobvious difference exists between the claimed invention and prior art. Meierhoefer forms ampoules and is silent regarding the specific polymers forming the walls. However, Meierhoefer calls for plastic that effectively retains compositions, and suggests non-gas permeable packages (col. 2, lines 31-40). Examiner cites Pfeiffer as teaching the three claimed layers, namely the innermost, intermediate and outermost layers. Here, Pfeiffer answers the need of Meierhoefer, namely gas and water impermeability (col. 2, lines 49-62).

Response to Arguments

52. Applicant's arguments, see p. 6-10 filed 17 September 2009 with respect to the rejection(s) of claim(s) 1, 3-7, 11-13 and 15 under 35 USC § 103 over Meierhoefer, Pfeiffer and Louviere have been fully considered and are persuasive. Therefore, the rejection is withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Meierhoefer, Pfeiffer, Itoh and Louviere. Examiner cites Itoh as teaching an intermediate layer having the claimed relative thickness in the new grounds of rejection.

53. Applicant notes that the photographs filed with the Reply of October 21, 2008 are not a new drawings, but rather an attachment to the Declaration of Mr. Manabe filed with the Reply. The objection to the drawings is withdrawn and the Declaration has been considered.

54. Applicant contends that Peiffer lacks an intermediate layer having the claimed relative thickness. Applicant notes that instead, Pfeiffer discloses a Base layer A that is 94% of the total film thickness. Applicant reasons that the claimed range of intermediate layer thickness improves the operability of the plastic ampoule. Examiner interprets the claimed intermediate layer thickness as a result-effective variable, and cites Itoh as teaching a thickness range overlapping the claimed range.

55. Applicant asserts that Peiffer is nonanalogous art, since Peiffer is directed to a film used as a packaging material, while Meierhoefer forms a plastic vial. Examiner notes that Peiffer also solves the problem of resisting gas and water permeability, by including at least three layers in a plastic laminate. Additionally, Meierhoefer calls for gas and water impermeability, by optionally including impermeable packaging (col. 2, lines 49-62).

56. Applicant submits that Peiffer fails to remedy the deficiencies of Louviere, namely the relative intermediate layer thickness. Examiner also cites Itoh as teaching the relative intermediate layer thickness for claim 13 in the new grounds of rejection.

Conclusion

57. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

58. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich
Tel (571)272-2590
Fax 571-273-2590

59. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

60. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

61. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
3 December 2009